

REMARKS

Previously, Claims 1 and 10-36 were pending in this application. In the instant amendments, Claims 10, 13 and 14 have been canceled without prejudice to Applicants' right to pursue the subject matter of the canceled claims in related applications. Claims 15, 16 and 36 have been amended. After entry of the instant amendments, Claims 1, 11-12, and 15-36 will be pending and under consideration.

I. AMENDMENTS TO THE CLAIMS

In the instant amendment, Claims 15, 16 and 36 have been amended. Support for amended Claims 15 and 16 can be found in the specification as filed, for example, at page 6, lines 23-25. Support for amended Claim 36 can be found in the specification as filed, for example at page 2, lines 25-26.

The amendments do not introduce any new matter and are fully supported by the specification and claims as originally filed. Entry and consideration of the are respectfully requested.

No claim amendment fee is believed to be due.

II. THE REJECTION OF CLAIMS 10 AND 13-36 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH SHOULD BE WITHDRAWN

Claims 10 and 13-36 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. Without acquiescing to the propriety of this rejection, Applicants have canceled Claims 10, 13 and 14. Applicants have amended Claims 15 and 16 such that Claims 15 and 16, and their dependent claims no longer depend from Claim 10. Applicants submit that the rejection of these claims for lack of enablement is obviated by the amendment to these claims. Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 10 and 13-36 under 35 U.S.C. § 112, first paragraph.

III. THE REJECTION OF CLAIMS 1 AND 10-36 UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

Claims 1 and 10-36 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Shaikenov *et al.*, WO 99/43314 ("Shaikenov *et al.*"). Applicants submit that the rejection of Claims 10, 13 and 14 is moot in view of their cancellation. Applicants respectfully disagree with the rejection of Claims 1, 11, 12 and 15-36 under 35 U.S.C. § 102(b).

A. The Legal Standard

“For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.” *See In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir., 1990). Anticipation is not shown even when the differences between the claims and the cited reference are allegedly “insubstantial” and any missing elements could be supplied by the knowledge of one skilled in the art. *See Structural Rubber Prod. Co. v. Park Rubber Co.*, 223 U.S.P.Q. 1264, 1270 (Fed. Cir., 1984). Furthermore, in *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 U.S.P.Q. 253, 259 (Fed. Cir., 1985), the Federal Circuit explained that “a reference which does not satisfy one limitation of a claim does not anticipate.” Thus, a cited reference must describe each and every claim limitation in order to anticipate the invention as claimed.

B. Shaikenov et al. does not Teach Each and Every Element of the Amended Invention

Independent Claim 1 recites a method for treating cancer in an animal in need thereof. The method comprises administering to the animal a composition comprising an extract of *Inula britannica* in an amount sufficient to induce phosphorylation of Bcl-2, such that the cancer is treated. Claims 11, 12 and 15-36 ultimately depend from Claim 1.

Applicants respectfully submit that Shaikenov *et al.* does not teach or suggest each and every element of Claims 1, 11, 12 and 15-36. Specifically, Shaikenov *et al.* does not teach or suggest a method for treating cancer in an animal in need thereof, comprising administering a composition comprising an extract of *Inula britannica* in an amount sufficient to induce phosphorylation of Bcl-2. Shaikenov *et al.* discloses a class of phosphosquiterpenes. *See Shaikenov et al.*, page 3, line 3, to page 14, line 11. This class of phosphosquiterpenes can function as farnesyl-protein transferase inhibitors. *See id.* at page 3, lines 9-12. However, Shaikenov *et al.* does not teach or suggest that this class of compounds, or any other compounds, can induce phosphorylation of Bcl-2 or should be administered in amount sufficient to induce phosphorylation of Bcl-2 for treating cancer. In fact, nowhere in Shaikenov *et al.* does even mention Bcl-2 or phosphorylation of Bcl-2. Thus, Shaikenov *et al.* does not teach or suggest a method of treating cancer as recited by Claim 1.

In addition to the foregoing reasons, Applicants submit that Shaikenov *et al.* does not teach or suggest limitations recited in dependent claims, such as, for example, Claims 11 and 12. Claims 11 and 12 specify that the extract *Inula britannica* comprises 1-*O*-

acetylbritannilactone or 1,6-*O-O*-diacetylbritannilactone. Applicants submit that Shaikenov *et al.* does not teach or suggest a composition comprising 1-*O*-acetylbritannilactone or 1,6-*O-O*-diacetylbritannilactone as recited by Claims 11 and 12.

In addition to the foregoing reasons, Applicants submit that Shaikenov *et al.* does not teach or suggest limitations recited in dependent Claims 23-24. Claims 23 and 24 specify the composition administered as a dietary supplement. Applicants submit that Shaikenov *et al.* does not teach or suggest administering a composition comprising an extract of *Inula britannica* as a dietary supplement, as required by Claims 23 and 24.

In addition to the foregoing reasons, Applicants submit that Shaikenov *et al.* does not teach or suggest limitations recited in dependent Claims 25-35. Claims 25-35 specify the amount of the composition of the invention administered to a human. Applicants submit that Shaikenov *et al.* does not teach or suggest administering a composition comprising an extract of *Inula britannica* in an amount that produces at least a fifty percent (50%) decrease in cell viability of specific cells relative to a control, as required by Claims 25-35.

In view of the foregoing, Applicants respectfully submit that Shaikenov *et al.* does not teach or suggest each and every element of Claims 1, 11, 12 and 15-36. Accordingly, Applicants respectfully request the rejection of Claims 1 and 10-36 under 35 U.S.C. § 102 (b) be withdrawn.

IV. THE REJECTION UNDER OF CLAIMS 1 AND 10-36 UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN

Claims 1 and 10-36 stand rejected under 35 U.S.C. § 103(a) as being obvious over Shaikenov *et al.*, WO 99/43314 (“Shaikenov *et al.*”) in view of Zhou *et al.*, 1993, *Phytochemistry* 34(1):249-52 (“Zhou *et al.*”). Applicants submit that the rejection of Claims 10, 13 and 14 is moot in view of their cancellation. Applicants respectfully disagree with the rejection of Claims 1, 11, 12 and 15-36 under 35 U.S.C. § 103.

A. Legal Standard For Obviousness

To reject claims in an application under 35 U.S.C. § 103, the Patent Office bears the initial burden of establishing a *prima facie* case of obviousness. *In re Bell*, 26 USPQ2d 1529, 1530 (Fed. Cir. 1993); MPEP § 2142. In the absence of establishing a proper *prima facie* case of obviousness, applicants who comply with the other statutory requirements are entitled to a patent. *In re Oetiker*, 24 USPQ2d. 1443, 1444 (Fed. Cir. 1992). In order to establish *prima facie* obviousness, three basic criteria must be met.

First, the prior art, either alone or in combination, must teach or suggest each and every limitation of the rejected claims. *In re Gartside*, 53 USPQ2d 1769 (Fed. Cir. 2000). The teaching or suggestion must be found in the prior art and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991).

Second, the prior art must provide one of ordinary skill in the art with a suggestion or motivation to modify or combine the teachings of the references relied upon by the Patent Office to arrive at the claimed invention. When an obviousness determination relies on one reference, there must be suggestion or motivation to modify the teaching of the reference in the manner suggested by the Patent Office. *In re Grabiak*, 226 USPQ 870 (Fed. Cir. 1985). The suggestion or motivation to combine the references generally arises in the references themselves, but may also be inferred from the nature of the problem or occasionally from the knowledge of those of ordinary skill in the art. *WMS Gaming Inc. v. International Game Technology*, 51 USPQ2d 1385, 1397 (Fed. Cir. 1999). The mere fact that references could be modified or combined does not render the resultant modification or combination obvious unless the prior art also suggests the desirability of the modification or combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01.

Third, the prior art must provide one of ordinary skill in the art with a reasonable expectation of success. Thus, the skilled artisan, in light of the teachings of the prior art, must have a reasonable expectation that the modification or combination suggested by the Patent Office would succeed. *In re Dow*, 5 USPQ2d 1529, 1531-32 (Fed. Cir. 1988). If any one of three criteria are not met, *prima facie* obviousness is not established. *In re Grabiak*, 226 USPQ 870 (Fed. Cir. 1985).

**B. The References Cited by the Patent Office Fail to Teach
Each and Every Element of Claims 1, 11, 12 and 15-36**

Applicants respectfully submit that the references cited by the Patent Office are not sufficient to establish a *prima facie* case of obviousness against Claims 1, 11, 12 and 15-36. For example, the cited references do not teach or suggest each and every element of Claims 1, 11, 12 and 15-36.

As discussed above, Shaikenov *et al.* does not teach or suggest a method for treating cancer in an animal in need thereof, comprising administering a composition comprising an extract of *Inula britannica* in an amount sufficient to induce phosphorylation of Bcl-2. Neither does Zhou *et al.* provides the missing element. Zhou *et al.* merely discloses three sesquiterpene lactones isolated from *Inula britannica*. However, it does not teach or suggest

these sesquiterpene lactones isolated from *Inula britannica* can induce phosphorylation of Bcl-2 or should be administered in amount sufficient to induce phosphorylation of Bcl-2. In fact, nowhere in Zhou *et al.* does even mention Bcl-2 or phosphorylation of Bcl-2. Thus, the combined teaching of Shaikenov *et al.* and Zhou *et al.* does not teach or suggest a method for treating cancer in an animal in need thereof, comprising administering to the animal a composition comprising an extract of *Inula britannica* in an amount sufficient to induce phosphorylation of Bcl-2, such that the cancer is treated, as recited by Claim 1.

In addition, Applicants respectfully submit that the Patent Office has not provided any suggestion or motivation to combine Shaikenov *et al.* and Zhou *et al.*

Further, Applicants respectfully submit that the Patent Office has failed to show that there is any reasonable expectation of success in combining Shaikenov *et al.* and Zhou *et al.*

As such, Applicants submit that the Patent Office has failed to establish a *prima facie* case of obviousness against Claims 1, 11, 12 and 15-36. Accordingly, Applicants respectfully request that the rejection of Claims 1 and 10-36 under 35 U.S.C. § 103 be withdrawn.

V. DOUBLE PATENTING

Claims 1 and 10-36 stand rejected under the judicially created doctrine of obviousness-type double patenting over U.S. Patent No. 6,627,623.

Applicants respectfully request that this rejection be held in abeyance until the allowable subject matter is determined at which point Applicants will consider filing a terminal disclaimer over U.S. Patent No. 6,627,623 or taking appropriate actions to overcome the rejection.

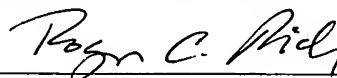
CONCLUSION

In view of the above amendments and remarks, Applicants believe that the present claims meet all the requirements for patentability. Entry of the foregoing amendments and remarks into the file of the application is respectfully requested.

No fees, other than those associated with the petition to extend time, are believed to be due with this response. However, the Commissioner is authorized to charge all required fees, or credit any overpayment, to Jones Day Deposit Account No. 50-3013 (referencing 517019-999019).

Date: January 31, 2006

Respectfully submitted,



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